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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/932,367	08/17/2001	Simon J. Rhodes	053884-5003	5068
28977	7590	10/06/2003	EXAMINER	
MORGAN, LEWIS & BOCKIUS LLP 1701 MARKET STREET PHILADELPHIA, PA 19103-2921			ZEMAN, ROBERT A	
			ART UNIT	PAPER NUMBER
			1645	7

DATE MAILED: 10/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/932,367

Applicant(s)

RHODES ET AL.

Examiner

Robert A. Zeman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 17 August 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-68 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-68 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

1. Claims 1-3, 5-9, 16 and 18, drawn to nucleic acids with a sequence with at least 80% identity to SEQ ID NO:1, vectors containing nucleic acids and recombinant cells containing said vectors, classified in class 536, subclass 23.1.
2. Claims 1-3, 5-9, 16 and 18, drawn to nucleic acids with a sequence with at least 80% identity to SEQ ID NO:13, vectors containing nucleic acids and recombinant cells containing said vectors, classified in class 536, subclass 23.1.
3. Claims 1-3, 5-9, 16 and 18, drawn to nucleic acids with a sequence with at least 80% identity to SEQ ID NO:15, vectors containing nucleic acids and recombinant cells containing said vectors, classified in class 536, subclass 23.1.
4. Claims 1-3, 5-9, 16 and 18, drawn to nucleic acids with a sequence with at least 80% identity to SEQ ID NO:7, kits and vectors containing nucleic acids and recombinant cells containing said vectors, classified in class 536, subclass 23.1.
5. Claims 1-3, 5-9, 16 and 18, drawn to nucleic acids with a sequence with at least 80% identity to SEQ ID NO:9, kits and vectors containing nucleic acids and recombinant cells containing said vectors, classified in class 536, subclass 23.1.
6. Claims 1-3, 5-9, 16 and 18, drawn to nucleic acids with a sequence with at least 80% identity to SEQ ID NO:11, kits and vectors containing nucleic acids and recombinant cells containing said vectors, classified in class 536, subclass 23.1.

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7. Claims 10 and 17, drawn to polypeptides encoded by a nucleic acid with the sequence of SEQ ID NO:1, classified in class 530, subclass 350.
8. Claims 10 and 17, drawn to polypeptides encoded by a nucleic acid with the sequence of SEQ ID NO:13, classified in class 530, subclass 350.
9. Claims 10 and 17, drawn to polypeptides encoded by a nucleic acid with the sequence of SEQ ID NO:15, classified in class 530, subclass 350.
10. Claim 11, drawn to polypeptides with the sequence of SEQ ID NO:2, classified in class 530, subclass 350.
11. Claim 12, drawn to polypeptides with the sequence of SEQ ID NO:8, classified in class 530, subclass 350.
12. Claim 12, drawn to polypeptides with the sequence of SEQ ID NO:10, classified in class 530, subclass 350.
13. Claim 12, drawn to polypeptides with the sequence of SEQ ID NO:12, classified in class 530, subclass 350.
14. Claims 13 and 15, drawn to antibodies that bind to polypeptides with the sequence of SEQ ID NO:1, classified in class 530, subclass 387.9.
15. Claims 13 and 15, drawn to antibodies that bind to polypeptides with the sequence of SEQ ID NO:13, classified in class 530, subclass 387.9.
16. Claims 13 and 15, drawn to antibodies that bind to polypeptides with the sequence of SEQ ID NO:15, classified in class 530, subclass 387.9.
17. Claims 13 and 15, drawn to antibodies that bind to amino acids 1-26 of SEQ ID NO:10, classified in class 530, subclass 387.9.

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18. Claims 13 and 15, drawn to antibodies that bind to amino acids 1-31 of SEQ ID NO:12, classified in class 530, subclass 387.9.
19. Claims 13 and 15, drawn to antibodies that bind to amino acids 1-29 of SEQ ID NO:14, classified in class 530, subclass 387.9.
20. Claims 13 and 15, drawn to antibodies that bind to amino acids 1-31 of SEQ ID NO:16, classified in class 530, subclass 387.9.
21. Claims 21 and 22, drawn to methods of detecting the presence of nucleic acids with at least 88.5% homology with SEQ ID NO:7 utilizing hybridization, techniques, classified in class 435, subclass 6.
22. Claims 21 and 22, drawn to methods of detecting the presence of nucleic acids with at least 88.5% homology with SEQ ID NO:7 utilizing PCR techniques, classified in class 435, subclass 91.2.
23. Claim 23, drawn to methods of detecting the presence of nucleic acids with at least 88.5% homology with SEQ ID NO:1 utilizing PCR, classified in class 435, subclass 91.2.
24. Claim 23, drawn to methods of detecting the presence of nucleic acids with at least 88.5% homology with SEQ ID NO:9 utilizing PCR, classified in class 435, subclass 91.2.
25. Claim 23, drawn to methods of detecting the presence of nucleic acids with at least 88.5% homology with SEQ ID NO:11 utilizing PCR, classified in class 435, subclass 91.2.

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26. Claim 23, drawn to methods of detecting the presence of nucleic acids with at least 88.5% homology with SEQ ID NO:13 utilizing PCR, classified in class 435, subclass 91.2.
27. Claim 23, drawn to methods of detecting the presence of nucleic acids with at least 88.5% homology with SEQ ID NO:15 utilizing PCR, classified in class 435, subclass 91.2.
28. Claims 24-25 and 32-33, drawn to methods of quantifying nucleic acids encoding mammalian Lhx3 utilizing PCR, classified in class 435, subclass 91.2.
29. Claims 29, 34 and 43, drawn to kits containing nucleic acids with the sequences of SEQ ID NO:34 and 35, classified in class 536, subclass 24.33.
30. Claim 29, drawn to kits containing nucleic acids with the sequences of SEQ ID NO:34 and 37, classified in class 536, subclass 24.33.
31. Claim 29, drawn to kits containing nucleic acids with the sequences of SEQ ID NO:36 and 35, classified in class 536, subclass 24.33.
32. Claims 29, 37 and 45, drawn to kits containing nucleic acids with the sequences of SEQ ID NO:36 and 37, classified in class 536, subclass 24.33.
33. Claim 30, drawn to kits containing nucleic acids with the sequences of SEQ ID NO:34 and 35 and an internal probe complementary to nucleotides 1-8867 of SEQ ID NO:2 , classified in class 536, subclass 24.33.
34. Claim 30, drawn to kits containing nucleic acids with the sequences of SEQ ID NO:34 and 37 and an internal probe complementary to nucleotides 1-8867 of SEQ ID NO:22 , classified in class 536, subclass 24.33.

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35. Claim 30, drawn to kits containing nucleic acids with the sequences of SEQ ID NO:36 and 35 and an internal probe complementary to nucleotides 1-8867 of SEQ ID NO:2 , classified in class 536, subclass 24.33.
36. Claim 30, drawn to kits containing nucleic acids with the sequences of SEQ ID NO:36 and 37 and an internal probe complementary to nucleotides 1-8867 of SEQ ID NO:2 , classified in class 536, subclass 24.33.
36. Claims 31 and 35, drawn to kits containing nucleic acids with the sequences of SEQ ID NO:34 and 35 and an internal probe with the sequence of SEQ ID NO:38, classified in class 536, subclass 24.33.
37. Claim 30, drawn to kits containing nucleic acids with the sequences of SEQ ID NO:34 and 37 and an internal probe with the sequence of SEQ ID NO:38, classified in class 536, subclass 24.33.
38. Claim 30, drawn to kits containing nucleic acids with the sequences of SEQ ID NO:36 and 35 and an internal probe with the sequence of SEQ ID NO:38, classified in class 536, subclass 24.33.
39. Claim 30, drawn to kits containing nucleic acids with the sequences of SEQ ID NO:36 and 37 and an internal probe with the sequence of SEQ ID NO:38, classified in class 536, subclass 24.33.
40. Claim 31, drawn to kits containing nucleic acids with the sequences of SEQ ID NO:34 and 35 and an internal probe with the sequence of SEQ ID NO:39, classified in class 536, subclass 24.31.

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41. Claim 31, drawn to kits containing nucleic acids with the sequences of SEQ ID NO:34 and 37 and an internal probe with the sequence of SEQ ID NO:39, classified in class 536, subclass 24.31.
42. Claim 31, drawn to kits containing nucleic acids with the sequences of SEQ ID NO:36 and 35 and an internal probe with the sequence of SEQ ID NO:39, classified in class 536, subclass 24.31.
43. Claims 31 and 38, drawn to kits containing nucleic acids with the sequences of SEQ ID NO:36 and 37 and an internal probe with the sequence of SEQ ID NO:39, classified in class 536, subclass 24.31.
44. Claims 31 and 36, drawn to kits containing nucleic acids with the sequences of SEQ ID NO:34 and 35 and an internal probe with the sequence of SEQ ID NO:40, classified in class 536, subclass 24.31.
45. Claim 31, drawn to kits containing nucleic acids with the sequences of SEQ ID NO:34 and 37 and an internal probe with the sequence of SEQ ID NO:40, classified in class 536, subclass 24.31.
46. Claim 31, drawn to kits containing nucleic acids with the sequences of SEQ ID NO:36 and 35 and an internal probe with the sequence of SEQ ID NO:40, classified in class 536, subclass 24.31.
47. Claims 31 and 47, drawn to kits containing nucleic acids with the sequences of SEQ ID NO:36 and 37 and an internal probe with the sequence of SEQ ID NO:40, classified in class 536, subclass 24.31.

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48. Claim 44, drawn to kits containing nucleic acids with the sequences of SEQ ID NO:36 and 35 and an internal probe complementary to a portion of the sequence of SEQ ID NO:9, classified in class 536, subclass 24.31.
49. Claim 46, drawn to kits containing nucleic acids with the sequences of SEQ ID NO:36 and 35 and an internal probe with the sequence of SEQ ID NO:11, classified in class 536, subclass 24.31.
50. Claims 39-42, drawn to methods of quantifying the level of Lhx3 expressed in a cell using reverse transcriptase PCR methods, classified in class 435, subclass 91.2.
51. Claims 48-51, drawn to methods of identifying a compound that affects the expression of human Lhx3 in a cell, classified in class 436, subclass 2.
52. Claims 52-54, drawn to methods of identifying a compound that affects the activity of human Lhx3 in a cell, classified in class 436, subclass 2.
53. Claims 55-56, drawn to methods of identifying a compound that affects the activity of human Lhx3 utilizing transfected cells, classified in class 514, subclass 44.
54. Claims 57-59, drawn to methods of identifying a compound that affects the DNA binding activity of human Lhx3 in a cell, classified in class 436, subclass 2.
55. Claims 60-63, drawn to methods of identifying a compound that affects the Lhx3 induction of a pituitary trophic hormone gene promoter in a cell, classified in class 436, subclass 504.

56. Claim 64, drawn to methods of identifying a human patient afflicted with a disease associated with altered expression of Lhx3, classified in class 436, subclass 2.
57. Claims 65-66, drawn to methods of identifying a human patient afflicted with a disease associated with altered level of Lhx3 binding to a nucleic acid, classified in class 436, subclass 504.
58. Claim 67-68, drawn to methods of detecting a mutation in an Lhx3 allele in a human, classified in class 436, subclass 504.

The inventions are distinct, each from the other because of the following reasons:

Inventions 1-20 and 29-49 are each separate and distinct from each other, as they comprise differing biochemical and immunological entities having differing properties and uses. In the instant case Inventions 1-6 are drawn to differing nucleic acids, while Inventions 7-13 are drawn to differing polypeptides, Inventions 14-20 are drawn to antibodies and Inventions 29-49 are drawn to differing combinations of nucleic acids.

Inventions 21-28 and 50-58 are each separate and distinct from each other as they are drawn to differing methods having different steps, different goals and leading to differing goals.

Inventions 1-58 are each separate and distinct from each other since aside from the specific compositions set forth in each groups the nucleic acids of groups 1-6 and 29-49, the polypeptides of Inventions 7-13 and the antibodies of Inventions 14-20 cannot be used in the methods of Inventions 21-28 and 50-58. With regard to the compositions specifically set forth in

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a given group, said Inventions are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids can be used for the recombinant production of a polypeptide, the polypeptides can be used for antibody production and the antibodies can be used in protein purification methodologies.

Because these inventions are distinct for the reasons given above and the search required for the aforementioned groups would not be coextensive in scope, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

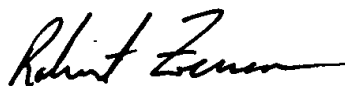
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (703) 308-7991.

The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read "Robert A. Zeman". The signature is fluid and cursive, with the first name "Robert" and last name "Zeman" clearly distinguishable.

Robert A. Zeman  
October 2, 2003